FORM PTO-1390 (Modified) (REV 10-95) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO (IF KNOWN, SEE 37 CFR
P00182US1	09/463024

INTERNATIONAL APPLICATION NO	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US98/14481	13 July 1998	14 July 1997

TITLE OF INVENTION

Hydroxycitric Acid Compositions, Pharmaceutical and Dietary Supplements and Food Products Made Therefrom, and Methods for Their Use in Reducing Body Weight

APPLICANT(S) FOR DO/EO/US

G. Ganga Raju

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S C. 371(c)(3)).
10. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 18 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
    A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☒ A substitute specification.
17. ☐ A change of power of attorney and/or address letter.
18. ☒ Certificate of Mailing by Express Mail
19. ☐ Other items or information:

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR) 09/465024	428 Rec'd PCT/PTO 14 JAN 2000 INTERNATIONAL APPLICATION NO. PCT/US98/14481	ATTORNEY'S DOCKET NUMBER P00182US1

20. The following fees are submitted:.

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

		CALCULATIONS PTO USE ONLY
☐	Search Report has been prepared by the EPO or JPO	**$930.00**
☐	International preliminary examination fee paid to USPTO (37 CFR 1.482)	**$720.00**
☐	No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))	**$790.00**
☐	Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO	**$1,070.00**
☒	International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)	**$98.00**

ENTER APPROPRIATE BASIC FEE AMOUNT =	**$96.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	**$0.00**	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =	0	x $22.00	**$0.00**	
Independent claims	- 3 =	0	x $82.00	**$0.00**	
Multiple Dependent Claims **(check if applicable)**.			☐	**$0.00**	
TOTAL OF ABOVE CALCULATIONS			=	**$96.00**	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) **(check if applicable)**.			☒	**$48.00**	
SUBTOTAL			=	**$48.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).			+	**$0.00**	
TOTAL NATIONAL FEE			=	**$48.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).**			☐	**$0.00**	
TOTAL FEES ENCLOSED			=	**$48.00**	
				Amount to be: refunded	$
				charged	$

☒ A check in the amount of **$48.00** to cover the above fees is enclosed.

☐ Please charge my Deposit Account No. in the amount of to cover the above fees.
A duplicate copy of this sheet is enclosed.

☐ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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30,507
REGISTRATION NUMBER

DATE

APPLICATION

for

UNITED STATES LETTERS PATENT

on

HYDROXYCITRIC ACID COMPOSITIONS, PHARMACEUTICAL AND DIETARY SUPPLEMENTS AND FOOD PRODUCTS MADE THEREFROM, AND METHODS FOR THEIR USE IN REDUCING BODY WEIGHT

by

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Number of drawing sheets: 0

Attorney Docket No: P00182US1

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Description

Hydroxycitric Acid Compositions, Pharmaceutical and Dietary Supplements and Food Products Made Therefrom, and Methods for Their Use in Reducing Body Weight

Technical Field

The present invention relates to hydroxycitric acid compositions, to dietary supplements and food products containing such compositions, and to the use of such compositions and products to reduce body weight in mammals.

Background of the Invention

Hydroxycitric Acid has been known for many years to be beneficial for the control and reduction of mammalian body weight. In particular, a specific stereoisomer of hydroxycitric acid, the (-)hydroxycitric acid isomer and derivatives thereof, is known to inhibit fatty acid and cholesterol synthesis and to function as a natural anorectic agent in mammals.

The stereoisomers of hydroxycitric acid are related structurally to citric acid wherein a hydroxy group is substituted for one of the four methylene hydrogens. Thus, there are four possible stereoisomers of hydroxycitric acid. Of these four stereoisomers, the (-) hydroxycitric acid isomer has been found to substantially inhibit fatty acid synthesis in biological systems in profused organs and intact mammals, and particularly in non-ruminant mammals.

It has also been known that the particular stereoisomer of interest, in both free acid and lactone forms, is found in the rind of the fruits of *Garcinia* species, for example, *Garcinia cambogia*, *Garcinia atroviridis* and *Garcinia indica*, which are native to the Indian subcontinent. The hydroxycitric acid component can be obtained by isolation from the fruit of *Garcinia* species using known procedures, for example Lewis, Y.S. "Methods in Enzymology" (J.M. Lowenstein, Ed., Vol. 13, pg. 613) (Academic Press, N.Y. 1969), and U.S. Patent No. 5,536,516.

As an inhibitor of the synthesis of fatty acids and cholesterol, hydroxycitric acid has been shown to significantly reduce the body weight and lower lipid accumulation in

rats. See, e.g. Sergio, W. *Medical Hypothesis* **27**:39 (1988), Sullivan, A.C., *et al.*, *Lipids* **9**:121 (1973), and Sullivan, A.C., *et al.*, *Lipids* **9**:129 (1973).

However, in order to formulate the compositions containing hydroxycitric acid into dietary supplements and food products, a number of desirable properties are sought. First, as most such supplements and food products are administered orally, the composition should have negligible odor and taste. Second, in order to increase the bioavailability of the hydroxycitric acid, the composition should be soluble in water. Solubility in water, as well as clarity in solution, are also important properties in many food and beverage applications. In addition, it is highly desirable that the composition be non-hygroscopic, in order to facilitate storage and formulation into dietary supplements and food products. Another desirable property is the hydroxycitric acid potency of the composition, where high potency levels are desirable.

Disclosure of the Invention

The present invention provides hydroxycitric acid compositions, food products made therefrom and methods for their use in reducing body weight.

In one aspect, the invention provides a hydroxycitric acid composition for reducing body weight wherein the composition comprises approximately 14 to 26% by weight of calcium, and approximately 24 to 40% by weight of potassium or approximately 14 to 24% by weight of sodium, or a mixture thereof, calculated as a percentage of the total hydroxycitric acid content of said composition.

In another aspect of the invention, a composition for reducing body weight is provided which comprises at least approximately 40% by weight of total hydroxycitric acids which further comprise approximately 5 to 13% by weight of calcium, and approximately 9 to 20% by weight of potassium or approximately 5 to 12% by weight of sodium, or a mixture thereof, calculated as a percentage of the total weight of said composition.

Additional aspects of the invention include dietary supplements and food products for use in reducing body weight which include the present compositions, and

methods for reducing body weight by administering such compositions, dietary supplements and food products to mammals.

Detailed Description of the Invention

The present invention provides hydroxycitric acid compositions, dietary supplements and food products made therefrom and methods for their use in reducing body weight. In one aspect, the invention provides a hydroxycitric acid composition for reducing body weight wherein the composition comprises approximately 14 to 26% by weight of calcium, and approximately 24 to 40% by weight of potassium or approximately 14 to 24% by weight of sodium, or a mixture thereof, calculated as a percentage of the total hydroxycitric acid content of said composition.

Hydroxycitric acid has been known for years to be useful for inhibiting fatty acid synthesis. Citrate is formed in the mitochondria by the citrate synthase reaction. It is then metabolized via the citric acid cycle. Under certain metabolic conditions, some citrate is diverted to the cell cytosol where it is used for fatty acid synthesis, that is, for energy storage. The inhibition of fatty acid synthesis in biological systems by the use of hydroxycitric acid is believed to arise from the inhibition of the citrate cleavage enzyme citrate-lyase by such compounds. The cleavage of citrate is catalyzed by citrate-lyase and citrate is the major source of the acetyl group of acetyl coenzyme A which is utilized in the conversion of carbohydrates and various amino acids to fats by non-ruminant mammals.

Typically, hydroxycitric acid is utilized in the form of its pharmaceutically acceptable, non-toxic basic salts. Such salts include, for example, the alkali metals, e.g. sodium and potassium, the alkaline earth metals, e.g. calcium and magnesium, and complex salts, such as ammonium or substituted ammonium salts.

In preparing various salts of hydroxycitric acid, it has been found that the pure potassium salt was highly soluble in water, but possessed high hygroscopicity, an undesirable property. It was also determined that the pure calcium salt was moderately soluble in water, and possessed minimal hygroscopicity, a desirable property.

Surprisingly, it has been determined that a mixture of calcium salt with potassium or sodium salts produces a composition which is highly soluble (up to 25% weight to volume in water), but with minimal hygroscopicity.

Furthermore, the composition according to the present invention displays minimal palatability concerns, as the taste of free hydroxycitric acid is almost entirely eliminated, as well as exceptional product application properties, including negligible odor, taste and color. While normally brown, the composition was found to be clear in solution.

In addition, the composition was found to be largely free of the lactone form of hydroxycitric acid, and that in solution it did not equilibrate between the free and lactone forms. Further desirable properties included a balanced pH, and a low (<1%) sodium content. Although sodium is an acceptable replacement for potassium in the present compositions, its inclusion is considered undesirable for considerations of minimizing dietary intake.

Thus the present compositions demonstrate a surprising, synergistic relationship between the calcium content and the potassium (or sodium) content. It has been determined that for a composition where the total hydroxycitric acid content exceeds 40% by weight, a total of salts of hydroxycitric acid which desirably comprise approximately 5 to 13% by weight of calcium, preferably approximately 7 to 13%, and approximately 9 to 20% by weight of potassium, preferably approximately 14 to 18%, or approximately 5 to 10% by weight of sodium, or mixtures of potassium and sodium. As stated earlier, although sodium is acceptable, it is considered desirable to minimize the content of sodium, desirably to less than 1% by weight.

It is further considered desirable to provide a composition in which the total hydroxycitric acid content is at least approximately 40% by weight, preferably at least approximately 50%, and desirably approximately 55-65%. Thus, in another aspect of the invention, a composition for reducing body weight is provided which comprises at least approximately 50% by weight of total hydroxycitric acids which further comprise approximately 5 to 13% by weight of calcium, and approximately 9 to 20% by weight of potassium or approximately 7 to 12% by weight of sodium, or a mixture thereof,

calculated as a percentage of the total weight of said composition. Of the total amount, it is also considered desirable that the amount of hydroxycitric acid in the form of the lactone not exceed approximately 2% by weight.

It is considered desirable to enrich the purity of free hydroxycitric acid from the Garcinia rind and prepare a calcium salt of the hydroxycitric acid. Generally, commercially available Garcinia rind comprises 25 to 30% moisture and 2 to 5% of sodium chloride. Garcinia rind contains 10 to 12% of free hydroxycitric acid, 12 to 15% of the lactone form of hydroxycitric acid and 2 to 3% citric acid on dry weight of the rind.

A further aspect of the preparation of the salt of hydroxycitric acid is to mask the sour taste of hydroxycitric acid, minimize the percentage of hydroxycitric acid lactone and prepare a sodium free salt of hydroxycitric acid. The process generally comprises washing the Garcinia rind, extracting hydroxycitric acid from the Garcinia rind, preparing an insoluble calcium salt of the hydroxycitric acid, dissociating the insoluble calcium salt and thereafter preparing calcium and potassium salts of hydroxycitric acid. The washing of the Garcinia rind is optional, as the sodium chloride can be reduced at other stages in the processing.

The salt free water extract can be obtained from salted Garcinia rind by washing the Garcinia rind followed by hot extraction. The dilute water extract is filtered through a filtrate after adding clay to the extract and settled. The filtered dilute extract is then concentrated to 45% total solids under reduced pressure at elevated temperature. This concentrate contains 10 to 12% of free hydroxycitric acid by weight, 11 to 13% of hydroxycitric acid lactone by weight and 2 to 3% of citric acid by weight.

The content of free hydroxycitric acid, hydroxycitric acid lactone, citric acid and non acid solutes can be determined by known techniques.

The process of enriching free hydroxycitric acid from the rind is accomplished by preparing a water extract of the rind, converting the extract into a insoluble calcium citrate and removing non acidic impurities in the extract, such as pectin, sugar and color which will solubilize, by washing the calcium hydroxycitrate. Thereafter, the calcium hydroxycitrate is dissociated with dilute phosphoric acid to form hydroxycitric

acid and calcium phosphate. The calcium phosphate is then filtered out and the enriched hydroxycitric acid solution is converted to highly soluble calcium salt by first adjusting the pH of the hydroxycitric acid solution to 3.5 to 5 with calcium hydroxide suspension and second by the addition of potassium hydroxide solution to adjust the final pH to 8.0 to 9.0. This calcium salt solution is then filtered and concentrated under reduced pressure to approximate 50% total solids. The concentrate is then treated with 75% alcohol/acetone to crystalize white crystalline highly soluble calcium salt.

There are numerous protocols available for preparing hydroxycitric acid extracts from Garcinia fruits. The rind of the Garcinia fruit which is commercially available typically consists of approximately 20% hydroxycitric acid, approximately 25% moisture and approximately 2.5% sodium chloride. It is considered desirable to eliminate as much sodium chloride from the rind as possible and since sodium chloride is freely soluble in water, this is easily accomplished. For example, one kilogram of raw Garcinia rind material is washed with approximately 2 liters of water in a stainless steel vessel. Thereafter, salt free Garcinia rind is extracted with 55 to 60°C water on a continuing basis with approximately 15 liters of water. The spent rind is then tested for hydroxycitric acid content and typically discarded. At this stage, recovery of total hydroxycitric acid is on the order of $90 \pm 2\%$.

Next, approximately 2.5 kilograms of Fuller's Earth (a kaolin containing an aluminum magnesium silicate) is added to the solution obtained previously. The mixture is stirred for one hour with continuous agitation at approximately 100 revolutions per minute then allowed to settle for two hours. Thereafter, the material is filtered through a bed of a filter aid in a centrifuge. The filtrate is concentrated to 800 grams of approximately 45% total solids containing approximately 22% total hydroxycitric acid content. The yield at this step is approximately 97% of the extracted hydroxycitric acid.

Next, the concentrated extract is filtered in a centrifuge to remove solids. To the filtered extract is added calcium hydroxide (100 grams in 500 ml of water). The mixture is stirred for approximately four hours maintaining the pH of the solution at

approximately 8.5. Thereafter, the mixture is filtered through the centrifuge and the supernatant is discarded. The moist pellet is washed continuously with 5 liters of water until the water is colorless and no solids are extracted from the filtrate. The yield of hydroxycitric acid at this phase is approximately 96.5%. In the next step, the wet pellet of calcium hydroxycitrate obtained previously is treated with 500 ml of 2N phosphoric acid solution to convert the calcium hydroxycitrate to hydroxycitric acid and calcium phosphate. Calcium phosphate precipitate is removed by centrifugation and washed with 2 liters of water. The filtrate contains approximately 165 grams of hydroxycitric acid with total solids of approximately 6.8% and the hydroxycitric acid yield is approximately 91.6%.

Finally, the hydroxycitric acid solution obtained previously is treated with calcium hydroxide (61.7 grams in 600 ml of water to adjust to pH 4.5). This solution is treated with neutral charcoal (60 grams at 75°C for two hours under agitation, cooled and filtered). To the filtrate is added potassium hydroxide (52 grams in 50 ml of water), which adjusts the pH to between 8.0 and 8.5. This salt solution is concentrated to 555 grams under reduced pressure to provide 50% total solids. The concentrate is treated with 75% acetone to obtain pure crystalline highly soluble calcium salt of hydroxycitric acid.

The amount of (-) hydroxycitric acid can be estimated by high pressure liquid chromatography (HPLC), generally as follows.

Estimation of (-) HCA by HPLC:

HPLC System:	SHIMADZU or equivalent
	LC 10AT Pump or equivalent
	SPD 10 Detector or equivalent
	CR 10A Software or equivalent
Column:	ALLTIMA C_{12} (5μ) (4.6x250 mm)
Wave Length:	210nm
Flow rate:	1mL/min
Volume of Injection:	20μL
Temperature:	$25° \pm 2°$C.
Mobile Phase:	0.05M sodium sulphate solution in water (pH adjusted to approximately 2.3 with conc. H_2SO_4).
Standards: 1)	Ethylenediamine Salt of (-) HCA.
2)	(-) HCA Lactone.

Standards Preparation: Weigh accurately about 50mg of each standard into two different 25mL volumetric flasks. Dissolve in water and make up to volume with water. Filter through 0.22μ membrane filter and inject the standard solutions separately.

Sample preparation: Weigh accurately about 50mg of sample in a 25mL volumetric flask. Dissolve it in water and make up the volume with water. Filter through 0.22μ membrane filter and inject the solution.

Retention Times: for free (-) HCA - 5 min.
(-) HCA Lactone - 4.1 min.

Calculations:

$$\% \text{ of Free (-) HCA} = \frac{\text{Sample Area x Standard Conc. x Purity of Standard}}{\text{Standard Area x Sample Conc.}}$$

$$\% \text{ of (-) HCA Lactone} = \frac{\text{Sample Lactone Area x Lactone Standard Conc. x Purity of Lactone}}{\text{Lactone Standard Area x Sample Conc.}}$$

REAGENTS

Unless otherwise stated all chemicals used are reagent grade.

- All glass washed with double distilled water.
- Dilute ammonia solution, 25% w/v.
- Ammonium chloride.
- EDTA
- Mordant Black T mixture
- Sodium sulphate, analytical grade, or equivalent
- Sulphuric acid, analytical grade or equivalent

WATER SOLUBLE EXTRACTIVES: As per USP XX.

pH : As per USP (1% Solution)

MOISTURE CONTENT : As per USP (K.F. Titrimeter)

CALCIUM: Weigh accurately about 10mg of sample into a 100mL conical flask, dissolve it in 50mL of water. Add 2mL of ammonia - ammonium chloride (pH 9.2) buffer. Then titrate with 0.01M EDTA solution. Using Mordant Black-T Mixture as indicator. End point is blue.

$$\% \text{ of Calcium} = \frac{\text{Titre value x Molarity of EDTA x 0.4 x 100}}{\text{0.01 x Weight of the sample in mg.}}$$

ESTIMATION OF SODIUM AND POTASSIUM BY FLAME PHOTOMETER:

Place 100mg of sample in a Silica crucible, and reduce to ash in a muffle furnace at 400°C. Transfer ash into a 50mL volumetric flask, add 1 drop conc. HCl and water to dissolve and make up to volume with water.

Calibrate the flame photometer with 100, 50 and 10ppm standard sodium and potassium solutions. Now place the sample solution in the flame photometer. Note the ppm reading corresponding to Sodium and Potassium.

$$\% \text{ of corresponding Ion} = \frac{\text{ppm reading corresponding Ion x 50 x 100}}{\text{1000 x Weight of sample in mg.}}$$

By inhibiting the synthesis of fatty acids, hydroxycitric acid is useful for the reduction of body weight in mammals. These useful compositions can be provided in the form of conventional pharmaceutical preparations or dietary supplements, for example, they can be mixed with conventional organic or inorganic inert pharmaceutical carriers or dietary supplements suitable for oral or parenteral administration, such as, for example, water, gelatin, lactose, starch, magnesium stearate, talc, vegetable oil, gums or the like. They can be administered in conventional forms, e.g., solid forms, for example powders, tablets, capsules, suppositories or the like; or in liquid forms, for example, suspensions or emulsions. In addition, such compositions can be formulated as a part of a processed food product for example in a form of a bar, baked good, beverage and the like.

Moreover, the pharmaceutical compositions and dietary supplements can be subject to conventional pharmaceutical or dietary supplements expedients, such as sterilization, and can contain conventional pharmaceutical or dietary supplements excipients, such as preservatives, stabilizing agents, emulsifying agents, salts for the adjustment of osmotic pressure or buffers, and the like. The compositions can also contain other therapeutically active materials.

A suitable dosage unit will typically contain from about 15 to about 3000mg of hydroxycitric acid, administered up to three times per day. Suitable parenteral dosage regimens in mammals can comprise from about 1mg per kilogram of body weight to about 50mg per kilogram of body weight per day. However, for any particular subject, the specific dosage regimen should be adjusted according to individual need and the professional judgment of the person administering or supervising the administration of the aforesaid compounds.

Additional aspects of the invention include food products and the like for use in reducing body weight which include the present compositions, and methods for reducing body weight by administering such compositions and dietary supplements and food products. When provided for oral administration as a processed food product, such as a beverage or a snack bar, the hydroxycitric acid content will desirably

comprise approximately 0.001 to 25%, preferably 0.05 to 5% by weight of the total weight of the food product.

Preparation of processed food products to include hydroxycitric acid compositions of the present invention involves, for example, diluting a concentrate of the composition containing at least approximately 40% hydroxycitric acid in water, adding supplements, blending, heating and/or periodic agitation.

For both snack bars and beverages, it is desirable to pre-pasteurize the concentrate in a highly diluted ratio with purified water. For example, approximately 1mL of the concentrate can be added to 12 fluid ounces of water. These figures will however vary depending upon the types of products desired, ranging from 1 to 25% for a beverage and 1 to 40% for a snack bar. After the blending step, the temperature of the vessel which the preprocessing step takes place is increased, frequently using steam as in the case of beverage manufacture or low heat as in the case of snack bars and baked goods. Before heat is applied, materials such as nutrients, antioxidants, vitamins and minerals can be added. In the production of the beverage, after the supplementation of the desired additives and achievement of homogeneosity, the liquid is pumped by a stainless steel pipeline into a bottling facility. High temperature steam is applied from the outside to the pipes which in turn maintains the temperature of the liquid during its transit. The pipes are placed so as to facilitate the bottling of the liquid beverage in an efficient manner.

In the preparation of, for example, snack bars, the preprocessing follows approximately the same protocol as for beverages. The environment for the development of this product is typically an industrial kitchen with the use of large cooking pots. The diluted hydroxycitric acid composition is blended with water, covered and heated, bringing it to a boil for a certain period of time. This boiling also provides agitation to insure thorough mixing. Thereafter, snack bars, baked goods or other processed food products are produced in accordance with the techniques well known in the art.

All patents and patent applications cited in this specification are hereby incorporated by reference as if they had been specifically and individually indicated to be incorporated by reference.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity and understanding, it will be apparent to those of ordinary skill in the art in light of the disclosure that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

Claims:

1. A hydroxycitric acid composition for reducing body weight wherein said composition comprises

a) approximately 14 to 26% by weight of calcium, and

b) approximately 24 to 40% by weight of potassium or approximately 14 to 24% by weight of sodium, or a mixture thereof,

each calculated as a percentage of the total hydroxycitric acid content of said composition.

2. A composition as recited in claim 1 wherein the sodium comprises less than approximately 2% by weight.

3. A composition as recited in claim 1 wherein the calcium comprises approximately 18 to 26% by weight.

4. A composition as recited in claim 1 wherein the potassium comprises approximately 28 to 36% by weight.

5. A composition as recited in claim 1 wherein the lactone forms of hydroxycitric acid comprise less than approximately 4% by weight of the total hydroxycitric acid content of the composition.

6. A dietary supplement composition for reducing body weight comprising a hydroxycitric acid composition of at least approximately 40% by weight of total hydroxycitric acid which further comprise approximately 5 to 13% by weight of calcium, and approximately 9 to 20% by weight of potassium or approximately 5 to 12% by weight of sodium, or a mixture thereof, each calculated as a percentage of the total weight of said hydroxycitric acid composition.

7. A composition as recited in claim 6 wherein the hydroxycitric acid composition comprises approximately 55-65% by weight.

8. A composition as recited in claim 7 wherein the calcium comprises approximately 9 to 13% by weight.

9. A composition as recited in claim 7 wherein the potassium comprises approximately 14 to 18% by weight.

10. A composition as recited in claim 6 wherein the lactone forms of hydroxycitric acid comprise less than approximately 2% by weight of the total weight of the composition.

11. A composition as recited in claim 6 wherein the sodium comprises less than approximately 1% by weight.

12. A food product for use in reducing body weight which comprises a prepared food product together with a hydroxycitric acid composition wherein said composition comprises at least approximately 40% by weight of hydroxycitric acid together with approximately 14 to 26% by weight of calcium, and approximately 24 to 40% by weight of potassium or approximately 14 to 24% by weight of sodium, or a mixture thereof, each calculated as a percentage of the total hydroxycitric acid content of said composition.

13. A food product as recited in claim 12 wherein the hydroxycitric acid composition comprises approximately 55-65% by weight.

14. A food product as recited in claim 13 wherein the calcium comprises approximately 18 to 26% by weight.

15. A food product as recited in claim 13 wherein the potassium comprises approximately 28 to 36% by weight.

16. A food product as recited in claim 12 wherein the sodium comprises less than approximately 2% by weight.

17. A food product as recited in claim 12 wherein the lactone forms of hydroxycitric acid comprise less than approximately 4% by weight of the total hydroxycitric acid content of the composition.

18. A food product as recited in claim 12 wherein said hydroxycitric acid composition comprises approximately 0.001 to 25% by weight of the total weight of said prepared food product.

19. A method for reducing body weight which comprises administering to a mammal in need of such treatment an effective amount of a hydroxycitric acid composition wherein the hydroxycitric acid content of said composition comprises approximately 14 to 26% by weight of calcium, and approximately 24 to 40% by weight of potassium or approximately 12 to 24% by weight of sodium, or a mixture thereof, each calculated as a percentage of the total hydroxycitric acid content of said composition.

20. A method as recited in claim 17 wherein the composition is administered to said mammal in the range of from approximately 1 to approximately 25 milligrams per kilogram of body weight of said mammal per day.

Abstract

Hydroxycitric Acid Compositions, Pharmaceutical and Dietary Supplements and Food Products Made Therefrom, and Methods for Their Use in Reducing Body Weight

Hydroxycitric acid compositions which comprise approximately 14 to 26% by weight of calcium, and approximately 24 to 40% by weight of potassium or approximately 14 to 24% by weight of sodium, or a mixture thereof, each calculated as a percentage of the total hydroxycitric acid content of the composition, together with dietary supplements and food products containing such compositions and methods for utilizing such compositions, dietary supplements and food products to reduce body weight in mammals are disclosed.

Docket No.
P00182US1

Declaration For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Hydroxycitric Acid Compositions, Dietary Supplements and Food Products Made Therefrom, and Methods For Their Use in Reducing Body Weight

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on _____ as United States Application No. or PCT International Application Number **09/463,024**

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
PCT/US98/14481	**PCT**	**13 July 1998**	☐
(Number)	(Country)	(Day/Month/Year Filed)	
(Number)	(Country)	(Day/Month/Year Filed)	☐
(Number)	(Country)	(Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, CFR Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

PCT/US98/14481	**13 July 1998**	**National Stage**
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
08/892,414	**14 July 1997**	**Abandoned**
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Sole or first inventor's signature — G. Ganga Raju — Date: December 11, 2001

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